- While the risk of contracting a foodborne illness from eating spinach is low, spinach and leafy greens have been associated with numerous outbreaks due to contamination with *E. coli* O157:H7.
- Many growers have adopted voluntary Food and Drug Administration guidelines (Good Agricultural Practices) to reduce the risk of microbial contamination.
- The foodborne illness outbreak linked to spinach forced the California spinach and the broader leafy green industry to consider new approaches to food safety.



JUNE 2007

OUTBREAK LINKED TO SPINACH FORCES REASSESSMENT OF FOOD SAFETY PRACTICES

On September 14, 2006, the U.S. Food and Drug Administration (FDA) announced that consumers should not eat bagged spinach because of an outbreak of illness due to con-

tamination with the potentially deadly bacterium *Escherichia coli* O157:H7. Stores and restaurants immediately cleared bagged spinach from their shelves and menus. Spinach harvesting and marketing ceased. There were no U.S. fresh spinach sales for 5 days, before FDA announced spinach from some areas was safe to consume. Spinach from the main production area of California was off the market for an additional 10 days.

By the time the outbreak was over, 204 people had become ill across 26 States and Canada, 104 had been hospitalized, 31 had developed the serious complication of hemolytic-uremic syndrome (HUS), and 3 had died (see box, "Escherichia coli O157:H7").

The Risk of Illness From Spinach Is Low

While spinach and other leafy greens have been associated with numerous foodborne illness outbreaks, the risk of becoming ill from spinach is low. In 2005, U.S. consumers ate 680 million pounds of fresh spinach, and the load of contaminat-

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ed spinach associated with the outbreak totaled only 1,002 pounds. But leafy greens are the most likely produce category to be associated with an outbreak. Since 1996, leafy greens have accounted for 34 percent of all outbreaks due to microbial contamination traced back to a specific fruit or vegetable, 10 percent of illnesses, and 33 percent of the deaths. Twenty of the 24 leafy green outbreaks in the United States since 1996 have been associated with E. coli O157:H7 contamination. But none of the previous outbreaks had the number of illnesses and deaths, publicity, market impact, or industry response of the 2006 outbreak associated with spinach. Only two outbreaks were associated with spinach, but they accounted for all five deaths associated with leafy greens over this period.

Many factors could influence the number of outbreaks traced to produce, but two are particularly relevant to spinach. First, consumption of produce has increased, as has the share consumed fresh. U.S. consumers are eating more spinach, up 90 percent since 1992, and eat-

ing more fresh—the most risky form for microbial contamination. In 2005, the average consumer ate 2.4 pounds of fresh spinach, up 180 percent since 1992. An

estimated 75-90 percent of fresh-market spinach is processed into fresh-cut salads or bagged spinach. Overall, consumption of processed spinach has trended downward since 1996. The heat used in processing kills *E. coli* O157:H7.

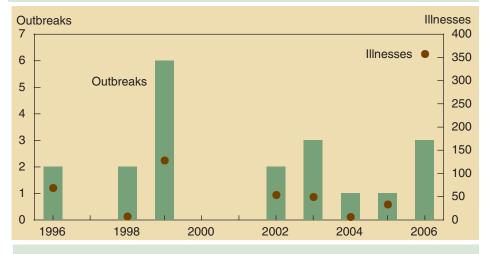
The second factor affecting the number of outbreaks is the increasing concentration within the produce industry. If something goes wrong at an operation handling a large volume of product, the number of ill consumers may be quite large and the outbreak may be more likely to be detected. For example, in the capital-intensive bagged-salad industry, two processing firms account for about 90 percent of the retail market.

The history of outbreaks associated with leafy greens has put pressure on the industry to improve food safety practices. Because most fresh produce is grown in a natural environment, it is vulnerable to microbial contamination. No set of practices would eliminate all risk because produce is not routinely treated with a "kill" process, like pasteurization for milk, which would eliminate microbial contaminants.

Escherichia coli O157:H7

Escherichia coli O157:H7 is a harmful bacterium that lives in the intestines of healthy animals, including cattle, deer, and wild pigs, and is excreted in their feces. Most E. coli, some of which live in the human intestine, are harmless to humans and known as generic E. coli. But E. coli O157:H7 causes diarrhea, often bloody. People become sick I-7 days after exposure, but usually within 2-3 days. Most healthy adults recover completely within a week, but E. coli O157:H7 can cause hemolytic-uremic syndrome (HUS), which can lead to kidney failure and even death. HUS is most likely to occur in young children and the elderly. The Centers for Disease Control and Prevention estimate that there are 73,000 infections and 61 deaths per year. The most common sources of outbreaks of E. coli O157:H7 in the United States include food (beef, leafy greens, sprouts, and unpasteurized juice) and water contaminated with feces, and animal contact. Fresh produce is now the leading cause of E. coli O157:H7 foodborne illness outbreaks in the United States.

E. coli O157:H7 illnesses linked to leafy greens reached new record in 2006



Source: U.S. Food and Drug Administration.

But voluntary FDA guidelines to *minimize* the risk of microbial contamination provide growers with a framework to use when developing their food safety plans. Many growers have sophisticated food safety programs. The conventional wisdom—there are no statistics—is that most large commercial growers of leafy greens have adopted voluntary FDA guidelines to reduce risk and use third-party audits to confirm that their practices are consistent with the guidelines. But outbreaks have continued. In an outbreak, some growers may not have used the guidelines or may not have used them consistently and correctly, or the

guidelines may not have addressed the specific mechanism of contamination for that particular outbreak. FDA investigations, industry efforts, and scientific research have not definitively explained how leafy greens became contaminated or how to avoid future contamination.

When planning their food safety programs, growers must consider the expected benefits and costs of an array of new, and perhaps costly, practices that they could adopt that may reduce their risk of contamination. In the past, growers generally did not receive a price premium for produce grown with safer practices, so



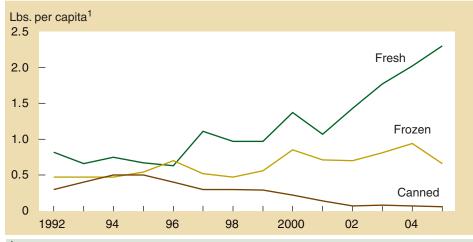
there was no immediate monetary benefit to offset the costs. There are important benefits, however, to adoption of improved food safety practices. Reducing outbreaks associated with a particular firm protects sales, reputation, and assets. Also, many retailers and foodservice buyers require that their suppliers use the voluntary FDA guidelines, so growers must adopt certain production practices to maintain wide market access—a very important incentive.

If this outbreak had been related to fresh bunched spinach, the traceback could have taken much longer.

The Outbreak

On September 11, 2006, the Centers for Disease Prevention and Control (CDC) received notice of an outbreak of foodborne illness in Wisconsin. Two days later, Wisconsin public health officials preliminarily linked the outbreak to bagged spinach based on epidemiological studies. Confronted with an escalating number of cases—50 illnesses in 8 States, including one death—the CDC feared that the outbreak was still developing and that contaminated spinach could still be in stores, restaurants, or consumers' refrigerators, posing a threat to public health. On September 14, the FDA announced that consumers should not eat bagged spinach; on the next day, it expanded its warning to all fresh spinach. FDA had never before made such a sweeping announcement about a U.S. fruit or vegetable. Usually, by the time an outbreak associated with fresh

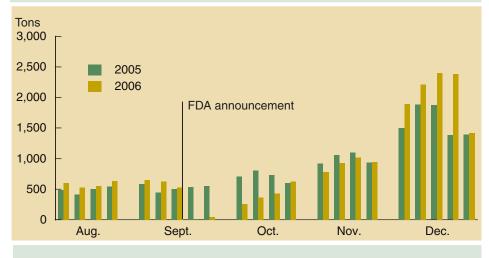
Fresh spinach consumption soars 180 percent since 1992



¹Fresh-weight basis.

Source: USDA, Economic Research Service, Vegetables and Melons Situation and Outlook Yearbook, 2006.

Weekly bunched spinach shipments rebounded after outbreak



Source: USDA, Agricultural Marketing Service, Market News Service.

produce is detected and the contaminated item is identified, the outbreak is over and the product in question has long since been consumed or discarded.

Most consumers remembered one brand of bagged spinach produced by Natural Selection Foods. Some sick consumers still had bagged spinach, with firm name and lot number, in their homes, providing FDA with a headstart in its investigation. If this outbreak had been related to fresh bunched spinach, the traceback could have taken much longer. On September 15, Natural Selection Foods recalled all of its production. This firm packed spinach products for 30 companies, including bagged baby spinach for Dole, which was eventually identified as the only contaminated product.

FEATURE

Records of Natural Selection Foods showed that four farms supplied spinach to the contaminated batch of bagged baby spinach. Eventually, FDA narrowed its focus to one farm and concluded that the problem probably originated there from field-level contamination. There were also factors that may have lead to the possible spread of contamination at the processing plant. Unfortunately, FDA could not determine exactly how the spinach became contaminated; even with rapid detection of the outbreak and a quick traceback, FDA arrived at the fields and processing facility 1 month after the contaminated spinach had been harvested and packed into bags.

Retail sales of bagged spinach and bagged salads with spinach have recovered more slowly than bunched spinach.

The contamination was traced to a load of spinach from one 2.8-acre field packed at one processing facility on August 15. This field was part of a 50.9acre parcel of land leased by a firm for leafy green production; the owner of the ranch used the rest of the property for grazing cattle. The leafy greens were grown with organic methods, but since the fields were only in the second year of the 3-year transition to organic, the spinach was sold as conventional. Organic, as well as conventional, operations must address the threat of microbial contamination. According to the California Food Emergency Response Team, the grower did not contract for a third-party audit for compliance with FDA's voluntary food



Tom Dodge, AgStockUSA

safety guidelines before the 2006 growing season began. Potential environmental risk factors at or near the field included the presence of wild pigs and irrigation wells near surface waterways exposed to feces from cattle and wildlife. The outbreak strain of *E. coli* O157:H7 was identified in samples of river water, cattle feces, and wild pig feces on the ranch; the closest contaminated sample was just under 1 mile from the spinach field. But the precise means by which the bacteria spread to the spinach remains unknown.

The FDA announcement initially closed down the spinach market. But on

September 29, FDA announced that "spinach on the shelves is as safe as it was before this event." Sales began to pick up, but recovery varied by type of spinach—bunched vs. bagged. USDA data on shipments of bunched spinach show that the market rebounded relatively quickly: in December, shipment volume was higher than in December of the previous year. Much of the adverse publicity focused on bagged spinach, not bunched spinach. But bunched spinach only accounts for an estimated 10-25 percent of the fresh spinach supply. Retail sales value data for bagged spinach and salads show a very different

story (USDA does not collect comprehensive shipment and price data on bagged spinach and salads). Retail sales of bagged spinach and bagged salads with spinach have recovered more slowly than bunched spinach. During the period January 24-February 24, 2007, 5 months after the outbreak, the value of retail sales of bagged spinach was still down 27 percent from the same period a year ago, although that was much improved from the low fall 2006 sales. Sales of bagged salads with spinach show similar trends. Sales of bagged salads without spinach were down 5 percent; part of the decline may be due to the spinach outbreak, but there were also two smaller outbreaks in late 2006 that were linked to lettuce that probably shook consumer confidence.

Voluntary "Good Agricultural Practices" Provide Guidance

In 1998, FDA published a voluntary guidance document "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," commonly known as Good Agricultural Practices, or GAPs. This was a general, commonsense guide because, at that time, there was very little specific research to provide more concrete advice. FDA promotes voluntary adoption of GAPs to minimize microbial contamination at the field level instead of relying exclusively on relatively ineffective testing to detect produce that might be contaminated. GAPs are now an important management tool used by growers in the United States and in foreign countries, especially where growers produce for the U.S. market.

In response to the continuing problems in particular sectors of the fresh produce industry, FDA has issued a series of warning letters and initiatives. In January 2004, FDA and CDC met with produce industry leaders to discuss numerous foodborne illness outbreaks associated with produce. At that meeting, industry

In 2007, bagged spinach and salad retail sales values still lag		
	Percent change in sales value from a year ago for:	
	January 24- February 24, 2007	August 24, 2006- February 24, 2007
		Percent
Bagged spinach	-27	-43
Bagged salad with spinach	-24	-42
Bagged salad without spinach	-5	-8
Source: Perishables Group, Facts, Figures & the Future.		

representatives agreed to take the lead on developing commodity-specific GAPs that would provide additional guidelines tailored to individual commodities that had been implicated in recent foodborne illness outbreaks. In April 2006, the produce industry put out its "Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain." The FDA developed the Lettuce Safety Initiative, and in August 2006, just at the time people were getting sick from spinach, the FDA, the California Department of Health Services, the California Department of Food and Agriculture, industry, and academics were meeting in California to discuss upcoming visits to lettuce operations to try to understand the contamination problem.

An Industry Under Pressure...

The California leafy green industry—growers, shippers, and bagged spinach and salad processors—is under strong pressure to avoid further outbreaks. The industry faces a barrage of demands for immediate improvements in food safety practices. FDA insisted that the spinach and leafy green industry take the lead in developing better food safety practices while holding out the prospect of mandatory regulation—something growers have traditionally tried to avoid. A group of retail and foodservice buyers demanded improvements in food safety. California State legislators called for tougher manda-

tory standards, and Congress scheduled hearings on food safety.

...Undertakes Initiatives To Regulate Itself...

With the fall 2006 outbreak, all spinach growers suffered from decreased consumer demand for their product, even though only one grower's spinach was contaminated. The California leafy green industry is trying to use the existing framework of State marketing agreements and marketing orders to regulate itself by encouraging all growers to adopt a baseline level of food safety practices. The two main challenges are identifying what practices will reduce the risk of future outbreaks at the minimum cost and getting all growers to adopt the practices. New practices may reduce risk, but they will undoubtedly raise costs and could bring structural change to the leafy green industry, as some growers find themselves with relatively higher costs than others.

The Western Growers Association, which represents fresh fruit and vegetable growers in California and Arizona, led the California leafy green industry's drive for self-regulation in California. In 2005, California accounted for 75 percent of total U.S. fresh-market production, and Arizona's winter production accounted for another 16 percent. The California Leafy Green Products Handler Marketing Agreement was approved in March 2007, under the supervision of the California



Department of Food and Agriculture. By April 1, 2007, the beginning of the first year of the agreement, 71 handlers representing more than 99 percent of all California leafy green production signed the agreement. Handlers of leafy greens firms that move the product from growers to retail and foodservice channels—who signed the agreement are obligated to handle California product only from growers who can show that they follow the Best Practices and use a traceback system recognized by the marketing agreement. Growers selling directly to consumers at roadside stands and in farmers' markets. generally small operations, are not covered by the marketing agreement because they are not considered handlers. Participation is voluntary, but once handlers sign up for the agreement, they must comply. Participation is an annual decision, so there is no guarantee that participation will remain at the current high level.

FDA could not
determine exactly
how the spinach
became contaminated.

For the marketing agreement, leafy greens are defined as iceberg, romaine, green leaf, red leaf, butter, and baby leaf lettuce; escarole; endive; spring mix; spinach; cabbage; kale; arugula; and chard. Imported leafy greens sold by participating handlers are not required to be produced with the Best Practices, but handlers may voluntarily use the guidelines for their imports (fresh-market spinach imports in 2005 accounted for about 4 percent of U.S. consumption). A charge of approximately 2 cents per 50 pounds of

product supports an inspection program to ensure compliance.

The California leafy green industry, with the help of scientists, developed the new Best Practices guidance document for California producers. This builds on the previous commodity-specific GAPs, which were intended to provide guidance for all growers of leafy greens. A marketing agreement is flexible, and Best Practices can evolve over time. The FDA reviewed the document, but it does not endorse private food safety plans. Some growers' practices already exceeded the Best Practices guidelines, while others had to upgrade their practices to comply. Retail and foodservice buyers concerned about food safety may accept the Best Practices as sufficient, but others may impose additional food safety requirements.

Unlike FDA's initial guidance document and the commodity-specific GAPs, the new Best Practices defines specific criteria and target values for controls and monitoring. For example, the original GAPs document warned farmers that "water quality should be adequate for its intended use." At the time, FDA was justifiably reluctant to specify what adequate water quality was because it did not have enough data to support specific thresholds. The new Best Practices are much more specific, but the science is still relatively weak. For example, the standards for well water require testing before production begins and monthly testing during the production season. The document recommends specific tests for measuring levels of generic *E. coli* (nonpathogenic *E.* coli) in the water and an action plan to be applied if counts reach certain numerical thresholds. The increased water testing is expected to be one of the more costly provisions of the Best Practices, and farmers would like to understand what the impact will be on risk levels. In the absence of more relevant science, the water standard is based on the Environmental Protection Agency's recreational water use standards. Also, while generic *E. coli* is a general indicator of fecal contamination or insanitary conditions, it is not a specific indicator for E. coli O157:H7.

Whoever sets the standards—industry or government—will have the same challenge: to develop science-based practices that reduce risk at the minimum cost.

Now that the California industry has implemented a marketing agreement, it is also considering a State marketing order. For a marketing order, growers would vote on whether they want to make Best Practices mandatory. A marketing order would apply to the whole industry, not just those who voted for it. To protect its competitive position and to minimize the risk of outbreaks elsewhere that would further shake consumer confidence in leafy greens, the California industry is considering whether to pursue a Federal marketing agreement or order that would cover the entire U.S. leafy green industry. In addition, the industry would like to find a mechanism to impose the same food safety standards on imports. Arizona producers are now considering a marketing agreement in their State.

...but Some Advocate **Mandatory Standards**

For the first time, some in the produce industry are calling for the Federal Government to step in and regulate food safety. In January 2007, the United Fresh Produce Association adopted a set of principles declaring that for food safety standards to be credible to consumers, they must be mandatory. Government approved, based on commodity-specific needs, applied consistently across producers of the same commodity, and subject to Federal oversight. This would resolve the problem that growers face of determining what level of precautions is enough. Support for this position probably varies among producer groups.

Whoever sets the standards—industry or government-will have the same challenge: to develop science-based practices that reduce risk at the minimum cost. Ongoing scientific research will contribute to this evolving process. In April 2007, Fresh Express, a large bagged salad company, distributed \$2 million of funding to support scientific research on E. coli O157:H7 in leafy greens. Scientists from universities, FDA, CDC, and the California Department of Health Services participated in the selection of the projects. The Center for Produce Safety was established in April at the University of California in Davis. This center is supported by pledges of over \$5 million from the Produce Marketing Association, Taylor Farms, Western Growers Association, the California Farm Bureau Federation, the California Department of Food and Agriculture, and the University of California. W

This article is drawn from ...

Background Information and Statistics: Fresh-market Spinach, available at: www.ers.usda.gov/news/spinachcoverage.htm

You may also be interested in ...

The Economics of Food Safety: The Case of Green Onions and Hepatitis A Outbreaks, by Linda Calvin, Belem Avendaño, and Rita Schwentesius, VGS-305-01, USDA, Economic Research Service. December 2004. available at: www.ers.usda.gov/publications/vgs/nov04 /vgs30501/

Traceability in the U.S. Food Supply: Economic Theory and Industry Studies, by Elise Golan, Barry Krissoff, Fred Kuchler, Linda Calvin, Kenneth Nelson, and Gregory Price, AER-830, USDA, Economic Research Service, March 2004, available at: www.ers.usda.gov/publications/aer830/

"Produce, Food Safety, and International Trade: Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce," by Linda Calvin, in International Trade and Food Safety: Economic Theory and Case Studies, edited by Jean Buzby, AER-828, USDA, Economic Research Service, November 2003, available at: www.ers.usda.gov/publications/aer828/aer828g.pdf.

The ERS Briefing Rooms on:

Traceability in the U.S. Food Supply, www.ers.usda.gov/briefing/traceability/

Vegetables and Melons,

www.ers.usda.gov/briefing/vegetables/

Industry Food Safety Actions, www.ers.usda.gov/briefing/industryfoodsafety/